

September 7, 1999

**VETERINARY SERVICES MEMORANDUM NO. 800.56**

Subject: Disposal of Unsatisfactory and Undesirable materials

To: Biologics Licensees, Permittees, and Applicants  
Directors, Center for Veterinary Biologics

**I. PURPOSE**

This memorandum establishes procedures to comply with 9 CFR 114.15 for the disposal of unsatisfactory biological products, carcasses, refuse, or materials unsatisfactory for production purposes.

**II. CANCELLATION**

This memorandum cancels Veterinary Services Memorandum No. 800.56 dated July 31, 1985.

**III. PROCEDURES**

A. Inactivation

Carcasses, contaminated material and byproducts, and unsatisfactory products containing live agents must be treated by one of the following approved inactivation procedures prior to disposal:

1. *Incineration* - The application of flame for a period of time sufficient to degrade all infectious organic material to a noninfectious state.

2. *Dry Heat* - The application of dry heat at a temperature of at least 160°C for a period of time (not less than 1 hour) adequate to inactivate, detoxify, and/or sterilize the material involved.

3. *Autoclaving* - The application of live steam at a temperature of at least 120°C for a period of time (not less than one-half hour) adequate to inactivate, detoxify, and/or sterilize the material involved.

4. *Chemical Inactivation* - The addition of formalin, phenol, cresol, beta-propiolactone, phenylmercuric nitrate, or equivalent inactivating agents at sufficient concentration for sufficient time and under proper conditions to inactivate, detoxify, and/or sterilize the material involved.

5. *Rendering* - The application of sufficient heat for a period of time sufficient to effectively destroy carcasses for human food purposes and to degrade

to a noninfectious state.

6. *Burial* - The internment of carcasses, contaminated feed, manure, bedding, and other items below ground level with sufficient covering material to prevent any further dissemination of microorganisms.

#### B. Disposal

1. *Live Agents and/or Toxins* - Treat materials containing live agents and/or toxins by an approved method listed in section III. A. of this memorandum before disposal. Other materials may be discarded without such treatment.

2. *Other Laws and Regulations* - Comply with all applicable Federal, State, and local laws and regulations pertaining to the disposal of waste and the maintenance of environmental quality in the final disposition of materials.

3. *Vehicles* - Transport infected carcasses or other infectious material using leak proof vehicles that are constructed and equipped to permit thorough cleaning and disinfecting.

#### C. Documentation

1. *Methods for Disposal* - Describe the method for disposal of material unsuitable for use in production in the Outline of Production.

2. *Records* - Maintain records according to 9 CFR 116.2.

3. *Supervision of Disposal* - Dispose of biological products found satisfactory by the licensee or permittee and found unsatisfactory by the Center for Veterinary Biologics (CVB) under the supervision of the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC). Unless CVB has authorized the licensee or permittee to dispose of such products without supervision, CVB personnel will witness destruction. In cases where the licensee or permittee is authorized to dispose of a serial, CVB will verify records during an inspection of the establishment and refer to this verification in the inspection report.

4. *Disposal by the Firm* - Report serials or subserials of biological product found unsatisfactory by the licensee or permittee on an APHIS Form 2008, Veterinary Biologics Production and Test Report. CVB will verify the destruction of the product during inspection of the establishment.

/s/

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Deputy Administrator  
Veterinary Services